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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,136	11/06/2006	David Wallach	30694/41887	3145

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,136	WALLACH ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,26-36 and 45-61* is/are pending in the application.

4a) Of the above claim(s) *26-36 and 45-61* is/are withdrawn from consideration.

5)☒ Claim(s) *13* is/are allowed.

6)☒ Claim(s) *1-10,12 and 14-19* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 02/17/2011, has been entered.

Claims 20-25, 37-44 and 62-63 have been canceled.

Claims 1-19, 26-36 and 45-61 are pending.

Claims 26-36 and 45-61 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1-19 are currently under examination as they read on an anti-NIK antibody that binds SEQ ID NO: 5, 6, and/or 3.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 02/17/2011.

The rejections of record can be found in the previous Office Action, mailed 08/31/2010.

3. The previous rejections under 35 USC 112, first paragraph, have been withdrawn in view of Applicant's amendment, filed 02/17/2011.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 6-10, 12, 14-16 and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (US 6,822,138 B1, see entire document).

Applicant's argument has been considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

> Schreiber taught a polyclonal antibody that binds specifically to NIK (see e.g., column 15, paragraph 4) and a pharmaceutical composition comprising the antibody as a modulator of NIK and a pharmaceutically acceptable carrier (see column 18, lines 41-49 and column 27, lines 32-43).
>
> Although Schreiber et al. did not teach the polyclonal antibody to NIK to bind specifically to a portion of NIK comprising phosphorylated threonine 559, given that polyclonal antibodies are known to bind multiple epitopes on one antigen, the prior art polyclonal antibody raised against NIK would necessarily bind to the epitopes comprising threonine 559. Therefore, the prior art antibody would be capable of specifically detecting phosphorylated NIK or a specific portion thereof by Western, ELISA or immunoprecipitation. Furthermore, the prior art antibody would also be able to regulate a biochemical activity of NIK because it is a polyclonal antibody that binds multiple epitopes on NIK which would the kinase activation site of NIK, thereby inhibiting the activity of NIK.
>
> Since the Office does not have a laboratory to test the prior art polyclonal antibody, it is Applicant's burden to provide objective evidence showing that Schreiber's polyclonal antibody raised against NIK does not bind to portions of NIK comprising phosphorylated threonine 559.

Applicant argues that Schreiber's polyclonal antibody does not anticipate the present claims because not all polyclonal anti-NIK antibodies specifically bind the phosphorylated version of NIK. Applicant relies on the instant specification for support of this argument by pointing to the definition of "specifically bind" and Figures 4 showing that antibody raised against SEQ ID NO: 3 phosphorylated at T11 only binds NIK phosphorylated at T559. In response, it is first noted that the claims do not specify a degree of binding thus read on any binding capacity, low or high. Furthmore, it is noted that the claims are drawn to any polyclonal antibody that binds SEQ ID NO: 5, 6 or 3 wherein the sequence comprises phosphorylated T559. While it acknowledged that SEQ ID NO: 3 is a 12 amino acids long epitope comprising phosphorylated T559, SEQ ID NOs: 5, however, is the full length NIK that is 947 amino acids in length. In view of the recitation of "and/or", the claims do not require the antibody to bind to the specific epitope set forth in SEQ ID NO: 3 but only that the sequence has to contain phosphorylated T559 residue. As SEQ ID NO: 5 is a 947-amino-acid-long polypeptide, a polyclonal antibody that binds NIK would bind to some epitopes in SEQ ID NO: 5.

Given that polyclonal antibodies bind multiple epitopes, Schreiber's antibody would necessarily bind to SEQ ID NOs: 5, 6, and/or 3. The burden was properly shifted to Applicant to provide object evidence of showing Schreiber's polyclonal antibody would not bind SEQ ID NO: 5, 6, and/or 3. The assertions of counsel cannot take the place of evidence in the record. Applicant's arguments have not been found persuasive. The rejection is maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Upon further consideration, the previous rejection under 35 U.S.C. 103(a) as being unpatentable over Schreiber et al. (US 6,822,138 B1) in view of Lin et al. (Mol Cell Biol. 1998, 18(10):5899–5907) and Campbell (*Monoclonal Antibody Technology*, 1984, Chapter 1, pages 1-32), Green (*JIM* 1999 231:11-23) on the grounds that it would have been obvious to make an antibody that binds to the activation loop of NIK comprising SEQ ID NO: 3 has been withdrawn in view of Applicant's remarks on that only fragments containing 549-560 (i.e., SEQ ID NO: 3) produced antibodies specific to phosphorylated NIK and that Lin did not teach or suggest the specific fragment set for in SEQ ID NO: 3.

8. The grounds of rejection for making antibody variants such as human antibody, humanized antibody, or antibody fragments and have been maintained as claims 1-10, 12, 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber et al. (US 6,822,138 B1) in view of Green (*JIM* 1999 231:11-23) and Owens et al. (*JIM*, 1994, 168:149-165). The rejection of record can be located in the previous Office Action, mailed 8/31/2011.

Applicant argues that the secondary references by Green and Owens fail to cure the deficiencies of Schreiber and Lin. In response, it is noted that Lin reference is not applicable to the rejection herein because the claims are drawn to antibodies that bind SEQ ID NO: 5, 6, and/or 3. Therefore, Schreiber's polyclonal antibody meets the claim limitation. The motivation and suggestion to make variants of antibody such as human antibody, humanized antibody, or antibody fragments have been rendered obvious by the combined teachings of the references. Therefore the rejection is maintained for reasons of record.

Conclusion

7. Claim 13 is allowed.
Claim 11 is objected.
Claims 1-10, 12, 14-19 have been rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Huynh N. Phuong can be reached on (571)272-0846. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Primary Examiner, Art Unit 1644